REMARKS/ARGUMENTS

Claims 1, 3, 5, 6 and 14-20 are pending in the application. In view of the finality of the Office Action, Applicants herewith, are filing a Request for Continued Examination and the appropriate fee. Applicants respectfully request entry of the following remarks.

Claim Rejections Under 35 U.S.C. §112

Claims 1, 3, 5, 6, 8 and 14-18 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Applicants respectfully traverse.

The Examiner asserts that the specification does not provide support for the instantly claimed invention. Specifically, "any drug candidate" and "differentiation of an embryonic stem cell into any type of cell." Applicants submit that the addition of any drug candidate that would be able to differentiate a stem cell into a specific type would be detected by the instant method. The important part of the test is whether the drug would or would not differentiate the cell. If the drug does differentiate the stem cell into a specific type then such a drug candidate is identified. If it does not then the drug would not be a candidate. The methods disclosed herein identify drugs which can differentiate the stem cell into just a hepatocyte. The nature of stem cells is, as disclosed by applicants, capable of differentiating into any type of tissue specific cells or cell types. The claimed subject matter clearly meets the requirements of the written description and enablement portions of 35 U.S.C § 112, first paragraph. Thus, one of ordinary skill in the art can use any drug that would need to be tested, follow the method as taught by applicants and determine if that drug causes the cells to differentiate. As such, the specification more than meets the standard for the written description requirement.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the instant rejection.

Claims 1, 3, 5-6, and 14-20 are newly rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the identification of substances which causes EBs to differentiate into hepatic lineage does not reasonably provide enablement for a method to screen for substances which cause differentiation into any lineage from EBs, or any tissue specific lineage from ES cells.

Applicants respectfully traverse.

Applicants have discussed the reasons above. Applicants submit that the addition of any drug candidate that would be able to differentiate a stem cell into a specific type would be detected by the instant method. The important part of the test is whether the drug would or would not differentiate the cell. If the drug does differentiate the stem cell into a specific type then such a drug candidate is identified. If it does not then the drug would not be a candidate. The nature of stem cells is, as disclosed by applicants, capable of differentiating into any type of tissue specific cells or cell types. The claimed subject matter clearly meets the requirements of the written description and enablement portions of 35 U.S.C § 112, first paragraph. With regard to meeting the enablement requirement of 35 U.S.C. 112, first paragraph, MPEP 2164.08 states that "[a]ll that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a 'reasonable correlation' to the scope of the claims. See, e.g., *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). See MPEP 2164.01 which cites *United States v. Telectronics, Inc.,* 857 F.2d 778,785,8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). MPEP 2164.01 further states that "[a] patent need not teach, and preferably omits, what is well known in the art." *In re Buchner,* 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991'); *Hybritech, Inc. v. MonoclonalAntibodies, Inc.,* 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied,* 480 U.S. 947 (1987); and *Lindemann Maschinenfabrjk GMBH v. American Hoist & Derrick Co.,* 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Regarding the test of enablement, MPEP 2164.05 states that "[t]he state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement. The state of the prior art is also related to the need for working examples in the specification." Regarding the presence of only one working example (i.e., a mercury response element), MPEP 2164.02 states that "[t]he presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure, even though it is a factor to be considered along with all the other factors. To make a valid rejection, one must evaluate all the facts and evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of the claims." As such, any compound can be tested without undue experimentation and determine whether that compound induces differentiation of the EBs, coupled with the level of skill in the art and the prior art at the time the application was filed, enables one skilled in the art to make and use the claimed invention. Regarding written description, the analysis of whether the specification complies with the written description requirement is conducted from the standpoint of one of skill in the art at the time the application was filed (see, e.g., *Wang Labs. v. Toshiba corp.*, 993 F.2d 858, 865,26 USPQ2d 1767, 1774 (Fed. Circ. 1993)) and should include a determination of the field of the invention and the level of skill and knowledge in the art. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986). The description need only describe in detail that which is new or not conventional. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1384, 231 USPQ at 94; Fonar *Corp. v. General Electric Co.*, 107 F.3d at 1549,41 USPQ2d at 1805. What is conventional or well known in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath,* 935 F.2d at 2563, 19 USPQ2d at 1116; *Martin v. Johnson,* 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972).

Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. See *Regents of the University of California v. Eli Lily & Co.,* 119 F.3d at 1568,43 USPQ2d at 1406. A "representative number of species" means that the species which are adequately described are representative of the entire genus. There may be situations where one species adequately supports a genus. See, e.g., *Rasmussen,* 650 F.2d at 1214, 211 USPQ at 326-27; *In re Herschler,* 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979); *In re Smythe,* 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973). What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. *In re Bell,* 991 F.2d 781, 785,26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird,* 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Circ. 1994). For these reasons, the enablement and written description requirements of 35 U.S.C. § 112 for each of the pending claims has been satisfied. Accordingly, withdrawal of these rejections and allowance of all pending claims is respectfully requested.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks and reconsideration and withdrawal of all rejections. It is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with the Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at telephone number shown below.

Although, Applicants believe that no extensions of time are required with submission of this paper, Applicants request that this submission also be considered as a petition for any extension of time if necessary. The Commissioner for Patents and Trademarks is hereby authorized to charge the amount due for any retroactive extensions of time and any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing or during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,
AKERMAN SENTERFITT

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